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Patrick Denis Lincoln

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,458

Applicant(s)

LINCOLN ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32,33,96,98,100 and 102-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-33, 96, 98, 100, and 102-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendments and remarks, filed 3/22/06, are acknowledged. Amended claims 32, 96, and 105-106 and cancelled claims 1-31, 34-95, 97, 99, 101, and 108-125 are acknowledged.

Applicant's arguments, filed 3/22/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 32-33, 96, 98, 100, and 102-107 are herein under examination.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-33, 96, 98, 100, and 102-107 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained for claims 32-33 and newly applied to claims 96, 98, 100, and 102-107.

Art Unit: 1631

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a program and model on a computer-readable medium, which may be construed to be a program and some data on a carrier-wave. As the computer-readable medium is not necessarily a physical object, it is not automatically statutory. Whether the claims are statutory therefore rests on whether the method/program is statutory. In the instant case, the program does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

Claims 32-33, 96, 98, 100, and 102-107 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

This rejection is maintained.

Claims 32-33, 96, 98, 100, and 102-107 are directed to an article comprising machine-readable media having an encoded model of a biological system.

It is not clear what one would use the model or program for. It is not clear what is the “practical” result of the encoded software. The “usefulness” of a model of a biological system is not apparent.

The instant invention involves a model of a biological system that undergoes substitutions of symbols representing biological elements. A model of a biological system is generally useful, but one of skill in the art would have to know something particular about the

Art Unit: 1631

model, such as tissue type, disease represented, or organism involved, in order for the utility to be specific. The specification on pages 26-27 states that the model may be used for generating testable hypotheses, that is not a specific utility because it is generally applicable to models in general. As stated above, the claims and specification fail to state what specific hypothesis generation might be tested. The specification on pages 26-27 states that the model may be used for diagnostics; however, the claims do not recite any diagnostics, or more importantly, for WHAT the diagnostics would be used. The specification on page 28 states that the models could be used to predict disorders characterized by changes in cell proliferation, cell differentiation, cell adhesion, and hormone levels which are specific; however, the claims are not limited to a cell proliferation model (or a cell differentiation model, etc.). Instead, the claims merely recite a "biological" model, which IS generic. For example, one skilled in the art would not know how to use a model of gastric emptying to predict ANYTHING about cells or hormones. Also, the model, as claimed, is not limited to represent or to be associated with a disease or disorder. The specification on page 28 states the methods can be used to identify drug targets, but the model, as claimed, is not limited to be one representing ANYTHING to do with drugs (such as ADME properties, PK/PD properties, etc), nor is it limited to represent receptors or receptor binding for screening drug candidates, etc. Models that predict disease, changes in cell proliferation (e.g. apoptosis), and identify drug targets have a well-established utility. However, the claims are not directed to such models. As the CLAIMS recite only a generic "biological" model, the asserted utility is not consonant with what is claimed and the claims do not have a specific utility. The specification on pages 26 and 28 state that the models can be used for designing artificial regulatory circuits which again is not commensurate with what is actually claimed. A utility

Art Unit: 1631

does not need to be recited in the claims; however, the utility must be of “immediate benefit” to the public (which means one must be able to use the CLAIMED invention for the asserted utility without further experimentation).

Further, the claimed invention is not supported by a substantial utility, because no substantial utility has been established for the claimed subject matter. Deciding to how to use the claimed generic model would require further research to confirm a “real world” context of use. Applicants mention that on page 28, paragraphs 3 and 4, the identified altered elements are potential drug targets and that a drug that alters properties of the identified element should cause the disease cell to become normal; however, the CLAIMS do not recite any sort of drug or drug target. Moreover, if such assertions were recited in the instant claims, these assertions would clearly require further research to confirm that such elements were indeed drug targets. Further research would also be required to confirm the identification of an effective drug. Using a model without a specific and substantial utility does not define a “real world” context of use.

As set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), the “usefulness” of an invention must be immediately apparent to those familiar with the technological field of the invention. As further research would be required to “use” the model and program encoded in the claimed article, the apparent result of the model and program is not “immediately useful” and lacks utility

Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, substantial, and credible utility. Although it may be credible that the claimed invention has the

Art Unit: 1631

above mentioned utilities, the lack of a specific and substantial utility, as explained above, sufficiently supports this rejection.

Applicants summarize the rejection. Applicants argue that the Examiner states a contradiction in that a model of a biological system is generally useful. It is noted that this and other general utilities mentioned do not satisfy the requirement for patentable utility that requires a combination of a specific, substantial, and credible utility. Applicants argue that the invention is adaptable to various specific and unique applications such that a single specific molecule and a single specific receptor under study are application specific. This statement is found unpersuasive there is no recitation of a SPECIFIC molecule or ANY receptor recited in the instant claims. Applicants argue that a prima facie case has not been established. It is noted that the rejection above adequately states reasons for concluding that the invention lacks specific and substantial utility. Applicants' arguments are deemed unpersuasive for the reasons given above.

#### LACK OF ENABLEMENT

Claims 32-33, 96, 98, 100, and 102-107 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants submit that the utility has been shown regarding the 35 USC 101 rejection so that one skilled in the art would know how to use the claimed invention. This statement is found

Art Unit: 1631

unpersuasive as the invention is still considered to lack patentable utility. Therefore, one skilled in the art would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, Second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These rejections are maintained.

Claim 32 recites limitations “being expressed” (claim 32, line 5), “express” (claim 32, line 5), and “to infer” (claim 32, line 7) which lack clarity. It is unclear if these limitations are intended to be method steps in the claimed composition. It is unclear how these method step limitations limit the model. Clarification of this issue via clearer claim wording is requested.

Claim 33 is also rejected due to its dependency from claim 32.

Applicants submit that claim 32 clearly identifies acts performed with the article. This statement is found unpersuasive as it is still unclear how the acts limit the structural components of the model.



***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-33, 96, 98, 100, and 102-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Thalhammer-Reyero (US 5,980,096).

This rejection is maintained.

Thalhammer-Reyero discloses a hardware and software environments for their systems, graphical interfaces, and methods for graphic information storage and retrieval, visual modeling, and dynamic simulation of complex biochemical systems that can encode modeling and simulation knowledge in sets of icons connected in schematics (col. 4, lines 59-67; col. 8, lines 56-67; and col. 18, lines 13-19) as well as processor and program means (claim 72) which represents an article comprising machine-readable media having encoded thereon a model of a biological system (as stated in claim 32) and software configured to cause a processor to run a method (as stated in instant claims 32, 96, 105, and 106). Thalhammer-Reyero discloses representing characteristics of biochemical and cellular entities in the form of symbols as well as the parallel and serial sets of processes in which they interact (col. 5, line 63 to col. 6, line 6 and col. 6, lines 50-54) and intracellular signaling pathways and lists of cell types containing certain molecules (col. 10, lines 46-50 and col. 54, lines 6-9) which represents symbols representing one or more biological elements of a biological system in an initial hypothetical state and first and second sets of symbols from cells (as stated in instant claim 32). The list of cells containing

Art Unit: 1631

certain molecules (col. 10, lines 46-50) also represents one or more symbols in a first set being in a second set, as stated in instant claim 33. Thalhammer-Reyero discloses that these entities represented by icons may participate in synthesis, degradation, modifications, interactions and translocation processes and can change dynamically at run time (col. 6, lines 30-39).

Thalhammer-Reyero discloses inference engines that search for and execute relevant rules and methods that comprise rules and procedures that are object-oriented and applied to the bioObjects as well as creating and modifying models as needed based on experimentation based on these rules and interactions involving alternatives (abstract, col. 3, lines 59-62; col. 6, lines 39-45; and col. 10, lines 1-24) which represents substituting symbols, rules representing interactions between biological elements, and an inference engine to process rules for initial and alternative (modified) states, as stated in instant claim 32. Thalhammer-Reyero discloses describing characteristics of objects as symbols with text, values, variables, or other attributes (col. 6, lines 50-62) which represents the symbols being typed, as stated in instant claims 102, and 107. Thalhammer-Reyero discloses objects within classes as well as chemical processes and their participants arranged in hierarchies (col. 5, lines 1-16 and col. 6, lines 63-67) which represents an organization of hierarchical classes, as stated in instant claim 103. Thalhammer-Reyero discloses class hierarchy and performing methods attached to an object's class (col. 4, lines 1-11) which represents a symbol (object) being matched by another symbol (object) that is a member of the hierarchical class, as stated in instant claim 104. Thalhammer-Reyero discloses units of all variables in all bioPools connected to the same bioprocess have to be appropriately matched (col. 58, lines 58-62) which represents a symbol being matched to another symbol that is a member of the hierarchical class, as stated in instant claim 104. Thalhammer-Reyero

Art Unit: 1631

discloses mathematical models, manipulating data via operations, using methods associated with component icons and interconnecting each pool to several processes, using functions and graphical interfaces associated with each icon (abstract and col. 15, lines 32-34), and modes of operation and display including rule processing and relationships as well as formulas and functions (col. 37, lines 43-51) which represent one or more rules comprising an operator for expressing a relationship between biological elements and conforming to associative and commutative properties, as stated in instant claims 96. Thalhammer-Reyero discloses concurrently monitoring thousands of variables (col. 4, lines 23 and 39-40; col. 18, lines 35-37) and executing rules and procedures to implement different strategies concurrently over time supporting symbolic expression (col. 19, lines 18-25) which represents rules expressing concurrent state transitions, as stated in instant claim 98. Thalhammer-Reyero discloses iterating the process (col. 9, lines 57-59) which represents that some of the rules are not terminating. Thalhammer-Reyero discloses programming the models into networks of interacting pathways including feedback and forward loops (col. 6, lines 20-24), as stated in instant claim 100. Thalhammer-Reyero discloses a function involving an "if...then" statement (col. 52, lines 1-7) which represents a rule that is conditional. Thalhammer-Reyero discloses symbols representing entities participating in pharmacological reactions (col. 5, line 66 to col. 6, line 6 and col. 6, line 54) and pharmacological or other experimental molecules added to the system from an external environment (col. 59, lines 4-6) which represents a symbol that represents an exogenous agent. Thalhammer-Reyero discloses an inference engine that receives input from a user (col. 19, lines 28-34), iterating the process (col. 9, lines 57-59), inference engines that search for and execute relevant rules and methods that comprise rules and procedures that are object-oriented and

Art Unit: 1631

applied to the bioObjects as well as creating and modifying models as needed for experimentation based on these rules and interactions involving alternatives (abstract, col. 3, lines 59-62; col. 6, lines 39-45; and col. 10, lines 1-24; and Tables 54-55) which represents substituting symbols, rules representing interactions between biological elements, and an inference engine to process rules for initial and alternative (modified) states which simulates a biological reaction/system, as stated in instant claims 32, 96, 105, and 106. Thalhammer-Reyero discloses the use of a second set of variables (col. 60, lines 23-29) which represents a second set for a second state of a biological system, as stated in instant claim 105. Thalhammer-Reyero discloses comparing two lists of bioReservoirs and bioEntities (symbol sets), loops over all entities from a bioReservoirs and scans connections to certain classes (col. 96, lines 45-51; col. 97, lines 40-65; and col. 100, lines 23-57) which represents comparing a second set to one of the alternate states (as mentioned above), as stated in instant claim 105. Thalhammer-Reyero discloses scanning the density value of the bioReservoir according to a symbolic value of the abundance attribute in a normal state and then the inference engine scans values of other sources in alternative states to compare to a threshold parameter (col. 107, lines 7-67; col. 112, lines 30-33; Tables 56 and 58; Figures 27-28) as well as initial conditions of basal quantity such that scaled-value set of variables are constrained not to be less than 0 and only activating and deactivating certain groups (col. 113, lines 13-35) which represents maintaining value if it exceeds the threshold parameter, as stated in instant claim 106.

Thus, Thalhammer-Reyero anticipates the instant invention.

With respect to instant claim 32, Applicants argue that Thalhammer-Reyero does not teach a representation of compounds from multiple cells. Thalhammer-Reyero discloses representing characteristics of biochemical and cellular entities in the form of symbols as well as the parallel and serial sets of processes in which they interact (col. 5, line 63 to col. 6, line 6 and col. 6, lines 50-54) and intracellular signaling pathways and lists of cell types containing certain molecules (col. 10, lines 46-50 and col. 54, lines 6-9) which represents symbols representing one or more biological elements of a biological system in an initial hypothetical state and first and second sets of symbols from cells. With respect to instant claim 96, Applicants argue that Thalhammer-Reyero does not teach “associative and commutative” properties and then state the relevance of whether or not the number of elements is important. This statement is found unpersuasive as “associative and commutative” properties have been broadly and reasonably interpreted due to the lack of a clear and concise definition in the specification. Thalhammer-Reyero discloses mathematical models, manipulating data via operations, using methods associated with component icons and interconnecting each pool to several processes, using functions and graphical interfaces associated with each icon (abstract and col. 15, lines 32-34), and modes of operation and display including rule processing and relationships as well as formulas and functions (col. 37, lines 43-51) which represent one or more rules comprising an operator for expressing a relationship between biological elements and conforming to associative and commutative properties. With respect to instant claim 105, Applicants argue that Thalhammer-Reyero is silent with the comparison of states to determine if a given goal state has been reached. This statement is found unpersuasive as instant claim 105 does not recite “to determine if a given goal state has been reached”, but rather to compare the second set of

Art Unit: 1631

symbols to the terminal state or at least one of the alternative resultant states. Thalhammer-Reyero discloses comparing two lists of bioReservoirs and bioEntities (symbol sets), loops over all entities from a bioReservoirs and scans connections to certain classes (col. 96, lines 45-51; col. 97, lines 40-65; and col. 100, lines 23-57) which represents comparing a second set to one of the alternate states. With respect to instant claim 106, Applicants argue that Thalhammer-Reyero fails to teach performing iterative substitution of symbols until a terminal state or alternative resultant states are detected. This statement is found unpersuasive as Thalhammer-Reyero discloses iterating a process (col. 9, lines 57-59), inference engines that search for and execute relevant rules and methods that comprise rules and procedures that are object-oriented and applied to the bioObjects as well as creating and modifying models as needed for experimentation based on these rules and interactions involving alternatives (abstract, col. 3, lines 59-62; col. 6, lines 39-45; and col. 10, lines 1-24; and Tables 54-55) which represents iteratively substituting symbols, rules representing interactions between biological elements, and an inference engine to process rules for initial and alternative (modified) states which simulates a biological reaction/system. Applicants' arguments are deemed unpersuasive for the reasons given above.

### ***Conclusion***

No claim is allowed.

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tiffany Tabb whose telephone number is (571) 272-0556.

May 30, 2006

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
6/12/06